

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY PATENT  
LITIGATION

No. 04-MDL-01592

**PLAINTIFFS' SUPPLEMENTAL MEMORANDUM ADDRESSING  
THE FIRST AMENDMENT IMPLICATIONS OF THE  
COURT'S JUNE 23, 2004 PROTECTIVE ORDER**

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## **I. INTRODUCTION**

On June 23, 2004, the Court issued an interim order (the “Protective Order”) restricting distribution of the file history of U.S. Patent Application No. 08/477,159 (the “’159 file history”) to in-house and outside counsel for plaintiffs, and requiring references to the file history in court records to be filed under seal. Protective Order, ¶¶ 2, 5 (Court’s Docket No. 34). The Court further provided that violation of the Protective Order “may be deemed a criminal and/or civil contempt.” On the same day, the Court issued a separate order (the “Briefing Order”) expressing concern that the Protective Order “raises First Amendment concerns not addressed in the parties’ submissions to date” and requesting further briefing on the First Amendment implications. Briefing Order, at 1, 3 (Court’s Docket No. 33).

On the Court’s prompting, plaintiffs have investigated the First Amendment issues and have concluded that the Protective Order restricting dissemination of the contents of the ’159 file history raises serious First Amendment concerns. The Protective Order constitutes a prior restraint on speech, which can survive First Amendment scrutiny only if it is necessary to further a “state interest of the highest order.” Smith v. Daily Mail Publ’g Co., 443 U.S. 97, 104–05 (1979). Because the Protective Order does not promote a significant government interest, it is invalid. See Butterworth v. Smith, 494 U.S. 624, 632 (1990). Neither the Supreme Court decision in Seattle Times nor any other pertinent decision permits the suppression of plaintiffs’ right to disseminate information obtained outside the discovery process. This Court should therefore vacate the interim Protective Order it issued on June 23.

## **II. BACKGROUND**

On May 26, 2004, Biogen Idec MA Inc. (“Biogen”) and Genzyme Corp. (“Genzyme”) filed a reply in support of their joint motion for a temporary restraining order and preliminary injunction (“the Reply”). They attached as an exhibit an amendment in the ’159 file history,

which had been provided to their counsel by the Patent and Trademark Office (“PTO”).

Columbia does not dispute that the PTO provided portions of the ’159 file history to certain plaintiffs, and that none of the plaintiffs obtained the ’159 file history through discovery.

The specification of the ’159 application is identical to the disclosure of U.S. Patent Application No. 08/484,136, which issued as U.S. Patent No. 6,455,275 (“the ’275 patent”), the patent-in-suit. Columbia first disclosed this information to the PTO on February 25, 1980, almost a quarter of a century ago, and it became public no later than the issuance of U.S. Patent No. 4,399,216 (“the ’216 patent”) in 1983. (Most of it had already appeared by then in papers published by the inventors.)

Nevertheless, on June 10, 2004, Columbia moved this Court to seal the portions of the Reply containing the ’159 file history. The following day, the Court ordered supplemental briefing as to whether the Court had the authority to restrict access to the released portions of the ’159 file history and whether this issue was moot in light of the fact that counsel for plaintiffs had already distributed the ’159 file history to their clients. Columbia supplemented its briefing on June 15, and opposition briefs were filed June 18.<sup>1</sup> The Court issued the Protective Order and the Briefing Order on June 23, 2004. Plaintiffs respectfully submit this brief pursuant to the Briefing Order.

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<sup>1</sup> Additional facts relevant to this dispute are set out plaintiffs’ opposition briefs and are incorporated herein by reference. See Opp’n of Biogen and Genzyme to Columbia’s Emergency Mot. to Seal and Restrict Access, at 1–5 (Court’s Docket No. 27) (“Biogen Opp’n”); Amgen Inc.’s and Immunex Corp.’s Opp’n to Columbia’s Mot. to Restrict Access, at 1–3 (Court’s Docket No. 26) (“Amgen Opp’n”).

### **III. COLUMBIA’S REQUESTED PROTECTIVE ORDER IS AN IMPERMISSIBLE PRIOR RESTRAINT.**

#### **A. The Protective Order Is a Prior Restraint Subject To Exacting Scrutiny.**

The First Amendment prohibits government restrictions on dissemination of information unless the restriction is justified by a sufficiently important government interest. See U.S. Const. amend. I; N.Y. Times Co. v. United States, 403 U.S. 713, 714 (1971); Near v. Minnesota, 283 U.S. 697, 716 (1931). Of particular concern are so-called “prior restraints” on speech or dissemination of information. In re Providence Journal Co., 820 F.2d 1342, 1345 (1st Cir. 1986), modified on other grounds en banc, 820 F.2d 1354 (1st Cir. 1987). A prior restraint is a judicial injunction or other government action that prohibits speech before it is actually uttered, in contrast to a subsequent penalty (such as an action for damages) imposed upon speech already made. See Near, 283 U.S. at 706–15. The concern is that the consequences of the prior restraint—the threat of contempt, for example—will chill speech and thus restrict the dissemination of information more than might be necessary to prevent harm. See Neb. Press Ass’n v. Stuart, 427 U.S. 539, 559 (1976).

The Protective Order at issue here is a prior restraint on speech. See Okla. Publ’g Co. v. Dist. Court, 430 U.S. 308, 309 (1977); Providence Journal Co., 820 F.2d at 1345. While the Protective Order is in effect, counsel for plaintiffs who have reviewed the ’159 file history will conduct this litigation and advise their clients against the backdrop of possible criminal contempt sanctions if they err by providing too much information concerning the ’159 file history. Because of the requirement that information concerning the ’159 file history be filed under seal, the public and the press will also be restricted from learning information that could otherwise be discerned from the docket of this case. The Protective Order is therefore subject to “the most exacting scrutiny” and can be justified only by “a government interest of the highest order.”

Butterworth, 494 U.S. at 631–32 (state statute violated the First Amendment where it prohibited a grand jury witness from publicly disclosing his own testimony after the grand jury term ended).

Heightened scrutiny applies even where a government disclosure of a third party's information violated statutory requirements, as Columbia alleges here. In Oklahoma Publishing, for example, the Supreme Court struck down an injunction prohibiting the news media from publishing the name of a juvenile obtained in open court, even though under a state statute the juvenile court judge should have closed the trial to the public. See 430 U.S. at 309, 311–12. The court held that, once the truthful information was publicly revealed by the court, the court could not constitutionally restrain its dissemination. Id.; see also Proctor & Gamble Co. v. Bankers Trust Co., 78 F.3d 219 (6th Cir. 1996) (noting that issues concerning how materials are obtained by a party wishing to further disseminate them “are not appropriate bases for issuing a prior restraint”).

The First Circuit invalidated a similar injunction in Providence Journal, where the district court attempted to enjoin a newspaper from publishing information it obtained through a Freedom of Information Act (“FOIA”) request to the Federal Bureau of Investigation because a third party alleged that certain documents had been released in violation of his Fourth Amendment rights. See 820 F.2d at 1344–45. The court held that, whatever the legality of the government's surveillance or subsequent disclosure of the intercepted information, a prior restraint on the newspaper's publication of the information violated the First Amendment. See id. at 1353.

Public Citizen Health Research Group v. FDA, 953 F. Supp. 400 (D.D.C. 1996), discussed in the Court's Briefing Order, does not override this well-settled law. In that case, the Food and Drug Administration erroneously released confidential information of a third party in

response to a FOIA request, prompting the third party to seek a protective order limiting further distribution of the materials. The district court entered a protective order pending trial on the propriety of the disclosure. With one paragraph of discussion, the court rejected a First Amendment challenge to the protective order, holding that the restriction was not subject to heightened scrutiny and identifying no significant state interest. See id. at 401–02. The cursory analysis in Public Citizen, which was not reviewed on appeal, cannot be reconciled with the controlling Supreme Court and First Circuit precedent discussed above.<sup>2</sup>

**B. The Government Does Not Have A Significant Interest In Restricting Dissemination Of The '159 File History.**

Columbia cannot rebut the “heavy presumption against [the] constitutional validity” of the Protective Order because the government has no significant interest in prohibiting the further dissemination of the '159 file history. See N.Y. Times, 403 U.S. at 714 (quoting Bantam Books, Inc. v. Sullivan, 372 U.S. 58, 70 (1963)); see also Fla. Star v. B.J.F., 491 U.S. 524, 527, 541 (1989) (invalidating prior restraint on newspaper’s publication of information obtained from a report available in a sheriff’s department pressroom); Daily Mail, 443 U.S. at 102 (invalidating sanction on newspaper’s publication of the name of a minor obtained from questioning police and prosecutor); Rodgers v. U.S. Steel Corp., 536 F.2d 1001, 1007–08 (3d Cir. 1976) (protective order placed on a deposition exhibit revealing methodology used in out-of-court negotiations violated the First Amendment).

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<sup>2</sup> Although the protective order in Public Citizen was entered for a limited time—pending a bench trial that was scheduled less than four months away, 953 F. Supp. at 405 n.4—even temporary prior restraints are subject to heightened scrutiny and must serve a significant government interest such as national security or a criminal defendant’s right to a fair trial. See Neb. Press Ass’n, 427 U.S. at 559.



There is no government interest here that is remotely similar to those that have previously justified prior restraints. See, e.g., Ashcroft v. ACLU, 124 S. Ct. 2783, 2789–90 (U.S. 2004) (government interest in protecting children from materials with harmful sexual content); Neb. Press Ass’n, 427 U.S. at 562–68 (government interest in preserving criminal defendant’s right to fair trial); Near, 283 U.S. at 716 (national security). See generally N.Y. Times (national security).

Columbia attempts to justify its request for a protective order on the grounds that (1) the ’159 file history is confidential, (2) its disclosure would assist potential licensees in judging the value of a license on the ’159 application, and (3) Congressional policy militates against disclosure. See Mem. Supp. Columbia’s Emergency Mot. to Seal and Restrict Access, at 7–10 (Court’s Docket No. 10). None of these allegations, even if true, would suffice to overcome the heavy presumption against validity of this prior restraint on speech. Moreover, Columbia’s allegations are specious.

Given the background here, there is nothing confidential in the ’159 file history. The research reported in and underlying the ’159 application was published at least as early as 1983, when the ’216 patent issued with the identical specification, and well over 100 claims have issued based upon this specification. Columbia alludes generally to the presence of confidential information, but never makes any attempt to identify any such information specifically, or to identify any actual harm from its release. See, e.g., June 22, 2004 Hr’g Tr., at 154–56 (Tab 1).<sup>3</sup> Further, as discussed at length in previous briefs, Columbia has not taken reasonable steps to

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<sup>3</sup> Citations to new record sources are to the Appendix to Plaintiffs’ Supplemental Memorandum Addressing the First Amendment Implications of the Court’s June 23, 2004 Protective Order, filed herewith. Citations to materials appearing in that Appendix are either to the Declaration of Carla M. Levy contained therein, or to materials appearing behind a numbered tab. In the latter case, the material will be cited by title and tab number.

preserve the confidentiality of the '159 file history; to the contrary, it disclosed portions of the file history to Immunex Corp. while expressly disclaiming any intent to treat it as confidential as to licensees. See Amgen Opp'n, at 1–3; Biogen Opp'n, at 6–7.

Nor does Columbia's second justification carry any weight. Columbia claims a right to keep its potential patent claims secret in order to obtain an advantageous position in hypothetical licensing negotiations. Columbia's interest in protecting its "commercial self-interest simply does not qualify as grounds for imposing a prior restraint." Proctor & Gamble, 78 F.3d at 225. Certainly, the unspecified and wholly speculative commercial harm posited by Columbia through nothing more than attorney argument cannot justify encroachments upon plaintiffs' First Amendment rights. As the First Circuit has made clear, "[a]n individual's right to protect his privacy from damage by private parties, although meriting great protection, is simply not of the same magnitude" as that required to justify a prior restraint on speech. Providence Journal, 820 F.2d at 1350.

Third, no Congressional policy rises to the level necessary to justify a prior restraint on dissemination of the '159 file history in these circumstances. On the contrary, recent legislation illustrates that the government's interest is in fostering transparency, not secrecy, during patent prosecution. See 35 U.S.C. § 122(b) (pending patent applications now generally published eighteen months after filing). Moreover, the purpose of the old law requiring patent applications to be held in confidence by the PTO was to prevent "the patent laws from being frustrated by permitting inventors' discoveries to become public knowledge before a patent is secured." Lee Pharm. v. Kreps, 577 F.2d 610, 616 (9th Cir. 1978). Here, Columbia bears no risk that potential licensees will exploit confidential discoveries or ideas because the inventions were disclosed in the now-expired '216 patent, which became public more than twenty years ago. Columbia's

efforts to obtain new claims on previously disclosed technology simply do not implicate the considerations that led Congress to enact 35 U.S.C. § 122. In any event, the statute upon which Columbia relies is no different from the statute at issue in Oklahoma Publishing, where the Supreme Court held that the policy concerns underlying a statute requiring the sealing of juvenile court proceedings did not justify a prior restraint on dissemination of information disclosed in violation of the statute. See 430 U.S. at 310–12.

Restricting dissemination of the '159 file history is contrary to the public interest. The public has a significant stake in the taxpayer-funded research that underlies Columbia's '275 patent and the '159 application. The public also has a significant interest in monitoring Columbia's attempts to prolong its patent monopoly. Columbia's request in 2000 for special legislation to extend its patent term met with intense scrutiny and widespread public outcry (and was ultimately rejected by Congress). See Am. Compl., ¶¶ 26–29, 71–74 (Court's Docket No. 6). This litigation, in which plaintiff licensees challenge Columbia's second and even more audacious attempt to extend its patent term, has also attracted considerable media attention. See, e.g., Gary Stix, Working the System II: Corporate Greed No Longer Remains the Sole Domain of the Corporation, Sci. Am., Mar. 2004, at 41; Eliot Marshall, Depth Charges Aimed at Columbia's "Submarine Patent," Science, July 2003, at 448; Naomi Aoki, Biotech Firms Sue Columbia University, Boston Globe, July 16, 2003, at C1; Andrew Pollack, 3 More Biotech Firms File Suit Against Columbia Over Patent, N.Y. Times, July 16, 2003, at B2 (copies attached at Tab 2). The media attention this litigation has drawn demonstrates the strong interest in public access to Columbia's maneuverings in the Patent Office.

**C. Because It Was Obtained Outside The Litigation Process, The '159 File History Is Unlike The Pretrial Discovery Material At Issue In Seattle Times.**

As the Court recognized in the Briefing Order, because the '159 file history was obtained outside of discovery or other judicial process, cases such as Seattle Times Co. v. Rhinehart, 467 U.S. 20 (1984), are inapposite. In Seattle Times, a religious organization sought a protective order covering information obtained through the discovery process that revealed the names and addresses of the group's members, financial contributors, as well as other sensitive information. To demonstrate good cause, the organization submitted affidavits demonstrating that organization members had been subject to attacks, threats and assaults. The Supreme Court defined the critical question in the case to be "whether a litigant's freedom comprehends the right to disseminate information that he has obtained pursuant to a court order that both granted him access to that information and placed restraints on the way in which the information might be used." Id. at 32 (emphasis added).

The Seattle Times Court upheld a protective order limiting the dissemination of the personal information at issue on the ground that the information was obtained "only by virtue of the trial court's discovery process," which is "a matter of legislative grace." See 467 U.S. at 32, 36-37. The Court made clear, however, that a party subject to such an order "may disseminate the identical information covered by the protective order as long as the information is gained through means independent of the court's processes." Id. at 33-34 (emphasis added). It held only that "where . . . a protective order is entered on a showing of good cause as required by Rule 26(c), is limited to the context of pretrial civil discovery, and does not restrict the dissemination of the information if gained from other sources, it does not offend the First Amendment." Id. at 37 (emphasis added).

In Butterworth, the Supreme Court refused to extend Seattle Times to information obtained outside the discovery process. The issue in Butterworth was whether a reporter could be prevented from disclosing the substance of testimony he gave to a grand jury, which concerned information he had obtained independently of the grand jury proceeding. In invalidating this prior restraint, the Supreme Court explained:

In [Seattle Times] we held that a protective order prohibiting a newspaper from publishing information which it had obtained through discovery procedures did not offend the First Amendment. Here, by contrast, we deal only with respondent's right to divulge information of which he was in possession before he testified before the grand jury, and not information which he may have obtained as a result of his participation in the proceedings of the grand jury.

Id. at 632; see also Minneapolis Star & Tribune Co. v. U.S. Dep't of Interior, 623 F. Supp. 577, 578 (D. Minn. 1985) (refusing to apply Seattle Times and denying protective order for Bureau of Indian Affairs files that were disclosed after being removed from federal custody, and not obtained "by virtue of the trial court's discovery process").

#### **IV. CONCLUSION**

The Protective Order is a prior restraint on speech, subject to exacting scrutiny. In the absence of any government interest in restricting the First Amendment rights at issue here—much less a sufficiently important interest—the prior restraint should not stand. Accordingly, the Protective Order requested by Columbia and entered by this Court on June 23, 2004 should be vacated.

Dated: July 16, 2004

Respectfully submitted,

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